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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,997	06/21/2001	James Harrison Aylward	07404-003003	4738

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT PAPER NUMBER

1654

DATE MAILED: 12/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/888,997

Applicant(s)

Aylward

Examiner

Christopher Tate

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 15, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 33-95 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 33-95 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## DETAILED ACTION

### *Election/Restriction*

Upon further review, based upon the generic phrasing recited in independent claims 33 and 78, the Restriction requirement set forth in the previous Office action is hereby withdrawn in favor of the Restriction and Election of Species requirement set forth below which replaces the previous Restriction requirement:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 33-77 and 82-92, drawn to a method of stimulating the immune system using a singular compound, classified in class 514, subclass 100+.
- II. Claims 78-81, drawn to a method of stimulating the immune system via administering an effective amount of at least two compounds, classified in class 514, subclass 100+.
- III. Claims 93-95, drawn to a method of recruiting an immune cell to a region of application of an undefined compound by administering an effective amount of the undefined compound to the region, classified in class 424, subclass 725, for example.

The inventions are distinct, each from the other because of the following reasons:

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The method of Group I require the administration of an effective amount of one active compound (from among numerous distinct compounds recited therein), whereas the method of Group II requires the administration of an effective amount of a combination of at least two bioactive compounds (from among numerous distinct compounds recited therein). Further, the two or more bioactive compounds administered in the Group II method (from among the numerous compounds recited therein) do not necessarily include the singular compound of Group I. The method of Group III is drawn to the administration of an undefined compound (e.g., plant extract) which does not necessarily include any of the compounds of Groups I or II and, further, is directed to a different functional effect than that of Groups I and II. One would not have to practice the various methods at the same time to practice just one method alone.

This application also contains claims directed to the following patentably distinct species of the claimed invention:

If Applicant elects Group I above:

- A. stimulating the immune system using a jatropane compound, or derivative or salt thereof (e.g., as recited in claims 35-64) .
- B. stimulating the immune system using a pepluane compound, or derivative or salt thereof (e.g., as recited in claims 65-69).

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- C. stimulating the immune system using a paraliane compound, or derivative or salt thereof (e.g., as recited in claims 70-73).
- D. stimulating the immune system using a angeloyl-substituted ingenane compound, or derivative or salt thereof (e.g., as recited in claims 74-77).

If Applicant elects Group II above:

- E. stimulating the immune system using two or more compounds from among those recited (e.g., in claim 79 - i.e., Applicant is required to particularly elect two or more of the compounds recited therein).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e., if Applicant elects Group I, Applicant is also required to elect one of the compound species from A-D; if Applicant elects Group II, Applicant is also required to elect two or more particular compound species from among those recited - e.g., from those recited in claim 79) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, for Group I, claims 33, 34, and 82-92 are generic; and for Group II, claims 78 and 81 are generic.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.

A handwritten signature in black ink, appearing to be 'CR Tate', with a stylized flourish at the end.

Christopher R. Tate  
Primary Examiner, Group 1654